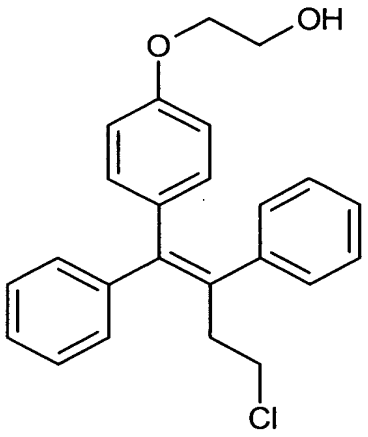
CLAIMS

1. A solid drug formulation comprising granulates containing a therapeutically active compound of the formula (I)



(I)

or a geometric isomer, a stereoisomer, a pharmaceutically acceptable salt, an ester thereof or a metabolite thereof, in combination with one or more intra-granular excipients.

2. The drug formulation according to claim 1 wherein compound (I) is ospemifene.

3. The drug formulation according to claim 1 wherein at least one intra-granular excipient is a disintegrant.

4. The drug formulation according to claim 1 wherein at least one intra-granular excipient is a diluent.

5. The drug formulation according to claim 1 wherein at least one intra-granular excipient is a binder.

6. The drug formulation according to claim 1 wherein the intra-granular excipient is
   a combination of at least one diluent and at least one binder;
   a combination at least one diluent and at least one disintegrant;
   a combination of at least one disintegrant and at least one binder; or

a combination of at least one diluent, at least one disintegrant and at least one binder.

7. The drug formulation according to claim 3 wherein the disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethylcellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

8. The drug formulation according to claim 4 wherein the diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calsium phospate and combinations thereof.

9. The drug formulation according to claim 5 wherein the binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

10. The drug formulation according to claim 1 wherein the granulates are made by dry granulation.

11. The drug formulation according to claim 1 wherein the granulates are made by wet granulation.

12. The drug formulation according to claim 1 wherein the formulation is a capsule comprising the granulates encapsulated in a shell.

13. The drug formulation according to claim 12 wherein the formulation comprises an extra-granular lubricant.

14. The drug formulation according to claim 13 wherein the lubricant is selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, a vegetable

oil, poloxamer, a mineral oil, sodium lauryl sulphate, sodium stearyl fumarate, zinc stearate and combinations thereof.

15. The drug formulation according to claim 1, wherein the formulation is a tablet comprising the granulates in combination with one or more extra-granular excipient.

16. The drug formulation according to claim 15, wherein the extra-granular excipient is selected from the group consisting of one or more disintegrants, one or more diluents, one or more binders, one or more lubricants, and their combinations.

17. The drug formulation according to claim 16, where the extra-granular disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethylcellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

18. The drug formulation according to claim 16, where the extra-granular diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calsium phospate and combinations thereof.

19. The drug formulation according to claim 16 wherein the extra-granular binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

20. The drug formulation according to claim 16 wherein the extra-granular lubricant is selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, a vegetable oil, poloxamer, a mineral oil, sodium laurul sulphate, sodium stearly fumarate, zinc stearate and combinations thereof.

21. The drug formulation according to claim 2 wherein 90 % of the drug substance has a particle size less than 250 micrometer.

22. The drug formulation according to claim 21 wherein 90 % of the drug substance has a particle size less than 150 micrometer and 50 % of the drug substance has a particle size less than 25 micrometer.

23. The drug formulation according to claim 22 wherein 90 % of the drug substance has a particle size less than 50 micrometer and 50 % of the drug substance has a particle size less than 15 micrometer.